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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,693	09/17/2003	Evgenu Nudler	NUDLER2A	3974

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,693	NUDLER ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28* is/are pending in the application.

4a) Of the above claim(s) *15-20 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 21-22, 25-26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All. b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-26 and 28 are pending.

This is in response to applicant's amendment filed on 07/13/07 in which claim 1 has been amended.

New claim 28 has been added.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-14, 21-22 and 24-27 under 35 U.S.C. 112 first paragraph has been withdrawn. However, a new rejection under 35 U.S.C. 112 first paragraph follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14, 21-22 and 24-26 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention for the reasons set forth in the previous office action mailed on 04/13/07.

Response to Amendment

Applicant's arguments filed 07/13/07 have been fully considered but they are not persuasive. Applicants argue that there is more than sufficient support in the specification for the rejection of certain phrases under 35 U.S.C. 112 first paragraph. In response, the rejection has been withdrawn.

With regard to the rejection of claims 1-14, 21-22 and 24-26, Applicants next argue that phrases like "perfluorocarbon" is defined in the specification as chemically inert, synthetic hydrophobic molecules that possess a unique capability for dissolving a variety of gases. This definition does not indicate what perfluorocarbon is because the metes and bounds of the word cannot be ascertained. No structure can be obtained from the specification to ascertain the exact structure of the "exact" perfluorocarbon. As previously stated in the prior office action, the term is very generic because the length of the carbon chain determines the physical properties of the specific fluorocarbon. Applicants have given examples or definition of what perfluorocarbons are without actually defining what it is.

With regard to the phrase metabolizing nitric oxide, the phrase does not indicate what diseases are being treated by controlling the metabolism of nitric oxide. The phrase appears to indicate a function and functional language at the pint of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly* and Co. 43 USPQ 2d. 1398 (CAFC, 1997) at 1406: stating this usage does "little more than

outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". A definition by function, as indicated, does not suffice to define the process. While there are lists of functional groups in textbooks as examples of such type of groups, the terminology requires testing to determine intended scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-14, 21-22, 24-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for regulating blood pressure, does not reasonably provide enablement for the use of perflourocarbons and the plethora of the intended use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims recite a method for controlling metabolism of nitric oxide by administering perfluorocarbon compounds and treating various disease states presumably associated with controlling the metabolism of nitric oxide. However, the specification only teaches the use of perftoran (a specific perfluorocarbon) to treat blood pressure. Therefore, the specification is not adequately enabled for using all

perluorocarbons and treating all the various diseases recited.

For example identifying a particular cancer requires knowledge of *in vivo* regeneration pathways, which is nothing short of extensive testing (none identified) herein.

Moreover, the plethora of intended uses renders the claims very ambiguous because there is no evidence of record to indicate any treatment for the various diseases recited. As pointed out previously, various cancers have different pathways and mechanisms of pathogenesis, which cannot be considered to be the same by any stretch of the imagination. There is no evidence for treating any disease let alone controlling the disease or the inception of the disease.

The reasons above also apply to autoimmune and immune diseases and resistance to infection.

Applicants have not provided any reasonable assurance that any and all known perfluorocarbon compound will have the ability to control metabolism of nitric oxide *in vivo* or in any biological process. It is not the norm that one can predict with any accuracy whether a particular perfluorocarbon compound will be more bioavailable without actual testing *in vivo*. The specification provides no guidance as to what other type(s) of (perfluoro compounds with the exception of perftoran) are suitable for controlling nitric oxide metabolism. Generally, the length of the perfluorated carbon chain determines what the physical properties and the utility of the perfluorocarbon will be.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be

considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is the use of perfluorocarbon compounds for treating various disease states. As stated, however, all fluoro compounds are also intended. The nature of the perfluoro compound is not set forth much less location of attachment.

2) State of the prior art.

The state of the prior art is that perfluoro compounds are known in the pharmaceutical industry.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue.

4) Level of predictability in the art.

The art pertaining to the use of perfluoro compounds and using the compounds

to treat various disease states is high as perfluoro compounds are specific and not all perfluoro compounds have the ability to treat the recited diseases.

5) Amount of direction and guidance provided by the inventor.

There is no guidance provided as all the examples in the specification are drawn to the reciting of presumably diseases to be treated by metabolizing nitric oxide.

6) Existence of working examples.

As discussed above, working examples are drawn to the use of perftoran to treat blood pressure on pages 33-37 of the specification and not to all perfluoro compounds treating all the recited diseases.

7) Breadth of claims.

The breath of the recited compounds and intended diseases render the claims overly broad.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high due to the unpredictability in the chemical art.

Therefore, as discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which prodrug can be used in the instant claim, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the word "perfluorocarbon" is of indeterminate scope because the word is very generic. Moreover, perfluorocarbons are compounds derived form hydrocarbons by replacement of hydrogen atoms with fluorine atoms. The length of the perfluorated carbon chain determines what the physical properties and the utility of the perfluorocarbon will be, e.g., perfluoro-propane is utilized during eye surgery. Note the selection of a particle size is not a patentable modification. See *In re Rose,* 105 U.S.P.Q. 237 (C.C.P.A. 1955).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS
September 13, 2007

James O. Wilson
Supervisory Patent Examiner
Art Unit 1624, Group 1600

Technology Center 1